DAIDS
Bethesda, MD USA

POLICY

Policy for Enrolling Children (including Adolescents) in Clinical Research: Protocol Document Requirements

Approval Date: 25 JUN 2009 No.: DWD-POL-CL-008.01A2
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Appendix 2
Examples of Templated Language

Risk categories:

1. Research not involving greater than minimal risk (45 CRF §46.404 and 21 CFR §50.51)

   Participation in this study poses no more harms or discomforts to research participants than they may experience in normal daily life or during routine physical or psychological examinations or tests.

2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants (45 CFR §46.405 and 21 CFR §50.52)

   Participation in this study involves procedures or interventions that are greater than a minor increase over minimal risk, but present the prospect of direct benefit to the individual child subjects.

3. Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition (45 CFR §46.406 and 21 CFR §50.53)

   The procedures/interventions in this study do not hold any direct benefit to the child participant, but present a minor increase in minimal risk and the prospect of yielding generalizable knowledge about the child's disease and/or condition.

Research not otherwise approvable

For research not otherwise approvable (45 CFR §46.407 and 21 CFR §50.54), consult with DAIDS Office for Policy in Clinical Research Operations (OPCRO) before proposing a study of this nature.

Parental/Guardian Permission Choices:

1. Minimal Risk (45 CRF §46.404 and 21 CFR §50.51)

   Permission will be sought from at least one parent or guardian in accordance with local IRB/EC approved procedures unless the IRB/EC has waived the requirements for obtaining parental or guardian permission in accordance with 45 CFR §46.408(c).

2. Greater that minimal risk (45 CFR §46.405 and 21 CFR §50.52)

   Permission will be sought from at least one parent or guardian in accordance with local IRB/EC approved procedures unless the IRB/EC has waived the requirements for obtaining parental or guardian permission in accordance with 45 CFR §46.408(c).

3. Greater than minimal risk, no benefit, but would yield generalizable knowledge (45 CFR §46.406 and 21 CFR §50.53)

   Permission will be sought from both parents or guardians in accordance with local IRB/EC-approved procedures unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child unless the IRB/EC has waived the requirements for obtaining parental or guardian permission in accordance with 45 CFR §46.408(c).

4. Research not otherwise approvable

   For research not otherwise approvable (45 CFR §46.407 and 21 CFR §50.54), consult with DAIDS OPCRO before proposing a study of this nature.

Child Assent Choices:

1. Assent not sought based on study risks and procedures/intervention

   Assent of the children involved in this study will not be sought because the IRB/EC waived the assent requirements in accordance with the regulations at 45 CFR §46.116(c), §46.116(d) or 21 CFR §50.55, unless required in accordance with local IRB/EC-approved policies and procedures.

2. Assent not sought based on age of children

Assent of some or all of the children involved in this study will not be sought because they are too young to be capable of providing assent, unless required in accordance with local IRB/EC-approved policies and procedures.

3. Assent not sought based on possible direct benefit only available from the research

   Assent of the children involved in this study will not be sought because there is the prospect of individual direct benefit that is important to the health/well-being of the children and is only available in the context of the research unless required in accordance with local IRB/EC-approved policies and procedures.

4. Assent to be sought

   Assent of the children involved in this study will be sought in accordance with the regulations at 45 CFR §46.408(a) or 21 CFR §50.55 and local IRB/EC-approved policies and procedures.